

REMARKS

Claims 1, 10, 11, 12, 18, 22 and 23 have been amended. No claims have been deleted. Claims 24-34 have been added. With entry of this amendment, claims 1-34 will be pending.

Applicant appreciates the Examiner's review and consideration of the information disclosure statement (IDS) filed on March 29, 2002. Consideration of the IDS timely filed on January 30, 2003 is also respectfully requested.

The Examiner's objection to the specification has been addressed by adding a paragraph pertaining to the "Cross-Reference to Related Applications."

Claim 18 and 23 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Periods have been inserted at the end of each of these claims to address this rejection.

Claims 1-4, 10, 12-15 and 22 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Appropriate amendment has been made.

Accordingly, withdrawal of the 112 rejections is respectfully requested.

Claims 1-23 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,376,528 issued to Gregory ("Gregory") in view of Billups, N.F. of the American DRUG INDEX 1998, 42nd edition ("Billups").

Gregory discloses a "method to suppress immune, acute or delayed-type hypersensitivity by treatment with a combination of a therapeutically-effective amount of a 5-lipoxygenase inhibitor and a cyclooxygenase-2 inhibitor." Abstract. "The method may be used, for example, to suppress the immune response associated with organ transplantation, graft versus host disease, and conditions with underlying autoimmune or inflammatory reactivities or responses." *Id.*

Billups discloses that minoxidil, topical, may be used for male pattern baldness. Page 488.

Independent Claim 1 and 12

Independent claim 1 recites, among other things, a method of treating hair loss comprising administering to a mammal an effective amount of the composition defined therein. The amount of composition administered is effective for treating hair loss.

Independent claim 12 recites, among other things, a method of treating hair loss comprising administering to a mammal an effective amount of the composition defined therein. The amount of composition administered is effective for treating hair loss.

Gregory and Billups, taken separately or combined, do not teach or suggest, or more importantly, enable, a method of treating hair loss comprising administering to a mammal an effective amount of a composition comprising the claimed compound.

More particularly, Gregory discloses a list of well over one hundred different organ transplantation procedures and disease states for which Gregory's compounds are purportedly useful. However, while using Gregory's compounds to treat alopecia may be mentioned, it is not enabled. For example, Gregory provides absolutely no dosage regimen for compounds intended to treat alopecia. In other words, Gregory never discloses what an effective amount would be to treat hair loss. Gregory does not provide any information regarding how the compounds should be administered with respect to alopecia, the effective amount of the compounds to be administered, or the frequency of administration. In other words, Applicant respectfully submits that one of ordinary skill in the art would be burdened with undue experimentation in view of Gregory, when determining how to actually effectively treat alopecia. The analytical methods set forth on pages 28-42 of Applicant's specification demonstrate the level of experimentation required to determine the proper dosage regimen for treating alopecia. Again, Gregory only mentions the word "alopecia."

Billups is directed only to minoxidil, and makes no mention of effective dosages of the claimed compounds.

To establish prima facie obviousness: 1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the teachings; 2) there must be a reasonable expectation of success; and 3) the references must teach or suggest all of the claimed limitations. MPEP 2142. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Applicant respectfully submits that a prima facie case of obviousness has not been established. More particularly, even assuming *arguendo* that the references are combinable and that a reasonable expectation of success would exist in combining them, the references still

would not teach or suggest each of the claimed limitations. In other words, Billups does not cure the enablement deficiencies of Gregory. In summary Gregory and Billups, taken separately or combined, do not enable a method of treating hair loss, and do not teach, suggest or enable an effective amount of a composition for achieving this goal.

Therefore, independent claims 1 and 12, as well as their dependent claims 2-9, 13-21, 24-29 and 31-33, are allowable. Reconsideration and allowance of these claims are respectfully requested.

Independent Claim 10

Independent claim 10 recites, among other things, a method of treating hair loss comprising administering to a mammal a composition comprising minoxidil and the claimed compound. The Examiner contends that Gregory teaches “treating alopecia with the ‘preferred’ pharmaceutical of tenidap.” Office action, page 4. Applicant has specified that the composition of claim 22 does not comprise tenidap.

Accordingly, independent claim 10 and its dependent claim 11 are allowable. Reconsideration and allowance of these claims are respectfully requested.

Independent Claim 22

Claim 22 specifies a composition consisting essentially of minoxidil and a compound having the claimed structure. Gregory only enables “treatment with a combination of a therapeutically-effective amount of a 5-lipoxygenase inhibitor **and** a cyclooxygenase-2 inhibitor.” Abstract, emphasis added. Gregory does not teach or suggest using a 5-lipoxygenase inhibitor and a cyclooxygenase-2 inhibitor separately. In fact, Gregory’s entire specification and claims require these two components be used together. The use of “consisting essentially of” transitional language renders the claim open for the inclusion of only unspecified ingredients that do not materially affect the basic and novel characteristics of the claimed composition.” *Dow Chem. Co. v. American Cyanamid Co.*, 615 F. Supp.at 484. This language excludes cyclooxygenase-2 inhibitors and lends patentability to the claim. In other words, assuming *arguendo* that Gregory and Billups are combinable, the combination would only yield a composition comprising a 5-lipoxygenase inhibitor, a cyclooxygenase-2 inhibitor **and** minoxidil.

Again, Applicant is claiming a composition consisting essentially of a compound having the claimed structure and minoxidil.

Accordingly, claim 22 and its dependent claim 23 are allowable. Reconsideration and allowance of these claims are respectfully requested.

Dependent Claims 24, 31 and 34

Dependent claims 24, 31 and 34 depend from allowable independent claims 1, 12 and 22, respectively, and therefore, are allowable for the reasons set forth above. In addition, claims 24, 31 and 34 are allowable because each contains additional patentable subject matter. More particularly, claims 24, 31 and 34 specify that the composition does not comprise tenidap. Therefore, for the same and similar reasons as set forth with respect to claim 10, these claims are further allowable. Reconsideration and allowance of these claims are respectfully requested.

Dependent Claims 25, 29, 30 and 33

Dependent claims 25, 29, 30 and 33 depend from allowable independent claims 1, 10 and 12, respectively, and therefore, claims are allowable for the reasons set forth above. In addition, claims 25, 29, 30 and 33 are allowable because each contains additional patentable subject matter. More particularly, claims 25, 29, 30 and 33 specify that the composition consists essentially of the compound. Therefore, for the same and similar reasons as set forth with respect to claim 22, these claims are further allowable. Reconsideration and allowance of these claims are respectfully requested.

Dependent Claims 26 and 27

Dependent claims 26 and 27 depend from allowable independent claim 1, and therefore, are allowable for the reasons set forth above. In addition, claims 26 and 27 are allowable because each contains additional patentable subject matter. More particularly, claims 26 and 27 specify administrations that are not taught or suggested by the combination of Gregory and Billups, assuming only *arguendo* that the references are combinable.

Consequently, claims 26 and 27 are allowable. Reconsideration and allowance of these claims are respectfully requested.

Dependent Claims 28 and 32

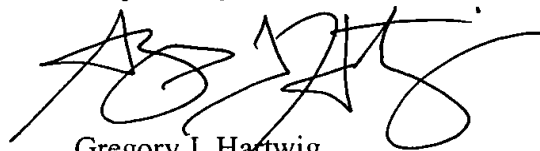
Dependent claims 28 and 32 depend from allowable independent claims 1 and 12, respectively, and therefore, are allowable for the reasons set forth above. In addition, claims 28 and 32 are allowable because each contains additional patentable subject matter. More particularly, each of these claims specify that an effective amount comprises about 5 mg to about 3000 mg. Gregory and Billups provide absolutely no dosage regimen for its compounds when treating alopecia. In other words, Gregory and Billups never disclose what an effective amount would be to treat hair loss. Neither provides any information regarding how the compounds should be administered with respect to alopecia, the effective amount of the compounds to be administered, or the frequency of administration.

Consequently, claims 28 and 32 are allowable. Reconsideration and allowance of these claims are respectfully requested.

CONCLUSION

In view of the foregoing, allowance of claims 1-34 is respectfully requested. Should the Examiner have any questions, he is strongly encouraged to contact the undersigned at the telephone number listed below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Gregory J. Hartwig', written over the printed name and registration number.

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